UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,636	11/18/2003	Martin Willard	10527-522001 / 03-257	4327

26161 7590 04/07/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
STIGELL, THEODORE J	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,636	WILLARD ET AL.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *26-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/9/06, 1/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5, 7, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (6,295,990). See Figure 15 and the respective portions of the specification. Lewis et al. disclose a method of cooling a target tissue region inside a body comprising providing a fluid cooled below body temperature (column 8, lines 1-9) and blood at a normal body temperature (blood delivered when balloon 606 is deflated) to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time, the temperature the tissue region with a target temperature range that is below normal body temperature, wherein when the balloon is deflated the blood and cooled fluid will be delivered simultaneously, wherein the providing of blood flow to the tissue region is performed by occluding a vessel upstream from the tissue region to restrict flow and then removing the occlusion to permit normal blood flow, wherein the catheter has a longitudinally extending lumen, the temperature of the region

is maintained between 25-36 degrees Celsius, and wherein the procedure is used to open a lesion, and wherein a control system controls the providing of fluid to the tissue region.

Claims 1-7,11-13,18-20, and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al. (2004/0167467 A1). Harrison et al. disclose a method of cooling a target tissue inside a body comprising providing fluid cooled below normal body temperature and blood at a normal body temperature to a target tissue to maintain the tissue at a temperature below normal body temperature. See page 2, paragraph 0032. The blood at normal body temperature is provided to the target tissue when the seal from the balloon (24) is removed. The blood at normal body temperature can also be provided to the tissue region by mixing it with the cool fluid which is usually saline and delivering the saline and blood together. See page 6, paragraph (0063). Harrison et al. also disclose that the providing of normal blood and cool fluid and the occlusion of the vessel is performed by a catheter (22) and balloon (24). Harrison et al. also disclose to maintain the tissue region between 28 and 36 degrees Celsius (page 1, paragraph (0003), use the procedure to open a lesion (page 7, paragraph (0072), and use a control system to provide fluid and blood.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but

not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10 and 21-23 are rejected under 35 U.S.C. 103(a) as being obvious over Lewis et al. (6,295,990).

In regards to claims 8-10 and 21-23, Lewis et al. disclose the invention substantially as claimed. Lewis et al. do not disclose the specific amount of time to maintain the temperature of the tissue below normal body temperature. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining the optimum results.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application Nos. 11/356,481 and 11/357,558. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Arguments

In the Remarks section, filed 1/17/2006, the Applicant contends that the Harrison reference is not considered prior art under any subsection of 35 USC 102, including

102(e). The Examiner respectfully disagrees and has maintained the 102(e) rejections of Harrison. As stated above and in the previous Office Action, the Applicant can only overcome the 102(e) rejection by filing a 37 CFR 1.132 or 1.131. There has been no submission of either document at the time of the instant Office Action. However, the Examiner has withdrawn all of the 103(a) rejections in view of Harrison because the conditions of 103(c) have been met.

Claims 1-13

In response to the Applicant's argument that Harrison does not disclose all of the limitations of claim 1, the Examiner respectfully disagrees. The Applicant contends that Harrison does "not involve providing both cooled fluid and normal-temperature blood to the target tissue region." The Examiner would first like to point out that "both" is not recited at all in claim 1. It is the position of the Examiner that cooled fluid is provided to the region through the catheter and then normal blood is provided when the balloon is deflated. This is the same method that is illustrated in Figures 1A-1B of the instant application.

The Applicant has also contended that cooled fluid and normal blood are not provided "in proportions to cool the tissue region and maintain, for an extended period of time, the temperature of the tissue region within with a target temperature range that is below normal body temperature". It is the Examiner's position that this limitation is extremely broad. There is no specific proportion, time period, or temperature range recited in this limitation. This limitation can even be met when the cooled fluid is delivered to the tissue region and the balloon is still inflated. The cooled fluid is

provided in a much greater proportion than the blood, which will reduce the temperature below a normal range for an extended amount of time.

Claims 18-20

The Examiner would like to clarify that the disclosure on page 6, paragraph 0063 was cited to support the anticipation of claim 18 and not claim 1.

In response to the Applicant's argument that Harrison does not disclose all of the limitations recited in claim 1, the Examiner respectfully disagrees. It is clear from the specification that the balloon will restrict normal blood flow and that blood can be mixed with cooled fluid delivered to the region.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Theodore J. Stigell

Theodore J. Stigell

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700